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Spiros Jamas

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,432

Applicant(s)

JAMAS ET AL.

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Previous Rejections

Unless specifically maintained infra, all previous rejections are withdrawn.

Since the new grounds of rejection which follow were not necessitated by Applicant's amendment, this action is NON-FINAL.

Enablement Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for aqueous soluble glucans in triple helix conformation which are immunostimulatory but do not induce the production of IL-1 and TNF, and/or which have high affinity for the glucan receptor on monocytes and enhance microbicidal activity of phagocytic cells and hemopoietic activity of monocytes, neutrophil and platelets, does not reasonably provide enablement for i) glucans of other conformations having such properties (instant claim 1) or ii) glucans in triple helix conformation which affect the immune system in more unspecified ways, *e.g.*, which only vaguely "mobilize normal immune defenses" (claim 4) or "enhance host defenses" without "inducing an inflammatory response" (claim 1) or "detrimental side effects" (claim 2). The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated that

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108 (1970). Keeping that in mind, the Wands factors are relevant to the

¹ As pointed out by the court in In re Angstadt, 537 F.2d 498, 504 (CCPA 1976), the key word is “undue”, not “experimentation”.

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instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The claimed invention relates to B-glucans which affect immune functions. The level of skill in the art is high, that of a PHD or MD. That factor is outweighed, however, by the high degree of unpredictability involved in the art.

The complexity and unpredictability of the immune system and therapies targeting it are well-known and reflected in the lack of effective treatments for many immunological disorders, from protozoal infections to type II diabetes to poison ivy dermatitis. Quite simply, one would not reasonably expect B-glucans as a class to exhibit the broad range of therapeutic efficacies embraced by the instant claims. Indeed, this understanding is reflected in Applicant's own specification; see, *e.g.*, the disclosure of page 5 *et seq.* which describes the "unique" set of biological properties of the instant B-glucans, which are produced using a "unique" series of acid and alkaline treatments which result in a triple helix conformation.

2. The breadth of the claims

Claim 1 is very broad with respect to both the B-glucan (the triple helix conformation is not specified) and immunological/therapeutic effect. Claims 2 and 4 are very broad with respect to immunological/therapeutic effect.

3. The amount of direction or guidance provided and the presence or absence of working examples

The instant specification provides guidance only for i) the use of B-glucans in the triple helix conformation to stimulate host immune systems without inducing IL-1 and TNF production, or ii) the use of B-glucans which in the triple helix conformation and which have a high affinity for the glucan receptor on monocytes, to enhance microbicidal activity of phagocytic cells and hemopoietic activity of monocytes, neutrophil and platelets. No direction is provided for inducing other broader immunological/therapeutic effects. The working examples provide data corroborating various specific immunological/therapeutic features as described, *e.g.*, failure to induce TNF production, (Table 4, page 24), but not more general immunological/therapeutic effects.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used for treating immune disorders in general as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "high" (affinity) in claim 3 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sugiura et al (USP 4,237,266).

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The patent discloses the treatment of cancer with underivatized, aqueous soluble B-glucans. Since the treatments are effective against spontaneous tumors (column 3, lines 25-27), they “enhance host defense mechanisms to infection” in a broad sense (where the spontaneous tumor is the “infective” agent). Nothing in the prior art indicates that they induce an inflammatory response.

Nonstatutory (Obviousness-Type) Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejections

1) Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,369,216.

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2) Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,811,542.

3) Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 81-87 of USP 5,783,569.

4) Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 20 of USP 5,322,841.

5) Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the pending claim of copending Application No. 11/333,765.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Discussion

Given the similarity of the various claims involved, the applications will be addressed together in the interest of economy.

All of the rejected conflicting claims recite B-glucans which were ultimately produced using the same "unique" series of alkaline and acid treatments described at the first paragraph of page 5 of the instant specification; they differ in each case only in the

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language used to characterize them. Accordingly, although the various claims are not identical *per se*, they are clearly drawn to substantially overlapping subject matter which provides coverage on substantially the same B-glucans. (The only exception are claims 81-87 of USP 5,783,569, which recite the presence of an "antimicrobial agent". Since the B-glucan itself is an antimicrobial agent, however, this recitation is not seen to distinguish those claims from claims reciting compositions containing only the B-glucan.)

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday-Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

